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Fax Cover Sheet

Date: 19 Nov 2003

To: Jill A. Fahrlander	**From:** Theodore J. Criares
Application/Control Number: 09/753,697	**Art Unit:** 1617
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Re:	**CC:**

☒ **Urgent** ☐ **For Review** ☐ **For Comment** ☐ **For Reply** ☒ **Per Your Request**

Comments:

Number of pages 7 **including this page**

CLAIMS 2-6, 11, 13-20, 25 AND 28-86 ARE PRESENTED FOR EXAMINATION

Applicants' request that the Final Rejection mailed August 13, 2003 be withdrawn is granted. This Office Action is the result of newly discovered art from Applicants portfolio which was not disclosed in either of applicants' IDS PTO-1449 forms.

Claims 15, 16,18-20, 25, 36 and 37 are withdrawn since they are drawn to a composition and are considered non-elected claims.

Claims 2-6, 11, 13, 14, 17, 28-35 and 38-86, are claims drawn to the elected method claims and have been examined by the examiner. This Office Action Is also the result of a telephone interview with the applicants' attorney who brought to the attention of the Examiner that they received an advisory relating to another's application and not one which addressed their Response of October 14, 2003.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2, 3, 38, 39, 40, 45, 46 and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment "of the various medical disorders set forth in the aforementioned claims, does not reasonably provide enablement for the "prevention" of the medical disorders set forth therein. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of treating or preventing various medical disorders in a subject with effective amounts of the claimed Vitamin D compounds. The nature of the claimed invention is extremely complex in that it encompasses the ***actual prevention*** of in some cases a cell proliferation disorder, such that the subject treated with above compounds does not cancer or any of the remaining claimed disorders.

Breath of the Claims: The complex of nature of the claims are greatly exacerbated by breath of the claims. The claims encompass prevention of a complex cell proliferation disorder or effectects on the immune system and bone in humans which has potentially many different causes. Each of which may or may not be addressed by the administration of the claimed compounds.

Guidance of the Specification: There is no guidance given by the specification as to the amount one would administer the claimed compounds to a subject in

order to actually prevent the claimed disorder. All of the guidance provided by the specification is directed towards treatment rather than prevention.

Working Examples: All of the working examples provided by the specification are directed toward the treatment rather than prevention..

State of the Art: While the state of the art is relatively high with regard to treatment of of medical disorders by administering Vitamin D compounds, the state of the art with regard to prevention of such disorders is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to prevent the medical disorders claimed by applicants..

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual prevention in a human subject with the claimed compounds makes practicing the claimed invention unpredictable in terms of prevention.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for prevention of the claimed medical disorders. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard prevention with any Vitamin D

compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding prevention with any claimed compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to prevent the development of the claimed disorders in a subject by administration of one of the claimed compounds. Therefore, a method of preventing in a subject administering any of the claimed Vitamin D compounds is not considered to be enabled by the instant specification..

Double Patenting

In accordance with the applicants request the prior cited patent was incorrect and the U.S. Patent No. 6,150,346 is correct.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Double Patenting rejection set forth in the Office Action of February 2, 2003, wherein claims of the present application are deemed to be obvious double patenting with respect to U.S. Patent 6,150, 346 (corrected citation) is maintained. Applicants'

claims 11 and 14 are deemed generic to applicants' claims since they claim "a 24-hydroxy Vitamin D" as the active agent.

Claims 2-6, 11, 13, 14, 17, 20, 28-35 and 38-86 are rejected under the judicially created doctrine of double patenting over claims 1-14 of U. S. Patent No. 6,242,434 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the claims in the application are drawn to a method of achieving an effect in a patient comprising administering an effective amount of a Vitamin D compound which is a 24-hydroxyvitamin D compound wherein the effect is treating or preventing bone loss or bone mineral content, hyperparathyroidism, hyperproliferation, or modulating the immune or inflammatory response. It would have been obvious to the skilled artisan to use applicants' claimed active Vitamin D agents, since it is taught at column 7, line 25 to column 8, line 25 and column 9, lines 15-32 of the patent, that the methods claimed in the present application would have the same effect with the compounds presently claimed. Further, it is to be recognized that this rejection is made to prevent the applicants from harrassing multiple assignees and presently rejected claims could have been have been claimed in the patent. This obvious type double Patenting rejection is deemed proper.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of

the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

None of the claims are allowed.

Applicants are again requested to review their portfolio of patents to determine if a possible Double Patenting situation should be brought to the Examiner's attention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 305-1877. The fax phone number for the organization where this application or proceeding is assigned is 703-746-6897.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Theodore J. Criares
Primary Examiner
Art Unit 1617

11/18/03
tjc